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| 09/895,381 | 07/02/2001 | Douglas C. Stahl | 2703.2 | 1421 |

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| EXAMINER |
|---|
| CLOW, LORI A |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | 10 |

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/895,381 | STAHL, DOUGLAS C. | |
| | Examin r | Art Unit | |
| | Lori A. Clow, Ph.D. | 1631 | |

*-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-48 is/are rejected.

7)☒ Claim(s) 25-36 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Claims 1-48 are currently pending in the instant application.

### *Claims Objections*

Claims 25-36 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 13-15, 18, 25-27, 30, 37-39, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewing et al. (Genome Research (1998) Vol. 8, pages 175-185).

Ewing et al. present an automated process for sequence data processing called *Phred.* In the analysis a gel image containing nucleic acid data is converted to an inferred base sequence (or read) for each template. The analysis consists of four distinct steps: lane tracking, in which lane boundaries are identified; lane profiling, in which each of the four signals is summed across

the lane width to create a profile, or trace, consisting of a set of four arrays indicating signal intensities at several thousand uniformly spaced time points during the gel run; trace processing, in which signal processing methods are used to deconvolve and smooth signal estimates, reduce noise, and correct for dye effects on fragment mobility and for long-range electrophorectic trends; and base-calling, in which the processed trace is translated into a sequence of bases (page 175, column 2). As required by claim 1, Ewing et al. describe a system in which nucleic acid data is in the form of a spatial domain (gel), data is transformed (mined), and sequence data is obtained. Furthermore, the spatial domain data is gained from gel electrophoresis and a machine-readable format is gathered from the image in the form of a chromatogram (page 176, column 1), as required by claim 2. The goal of the software is to actually produce a sequence as accurate as possible despite data problems, such as compressions, weak or variable signals, and trace spacing. This involves data normalization, as described in detail on pages 176, column 2 and 177, column 1 and required by claim 3. The transformation performed involves the use of the Fourier transformation, as required by claim 6, 18, 30, and 42 (see page 177, column 2).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-12 17-24, 29-36, and 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewing et al. (Genome Research (1998) Vol. 8, pages 175-185) in view of Youssef (A Lecture Series on Data Compression (translation 1996 by Speilman@NIST.GOV) pages 1-9) in view of Curram et al. (Journal Opl Res. Soc. (1994) Vol.45, pages 440-450).

Ewing et al. present an automated process for sequence data processing called *Phred.* In the analysis a gel image containing nucleic acid data is converted to an inferred base sequence (or read) for each template. The analysis consists of four distinct steps: lane tracking, in which lane boundaries are identified; lane profiling, in which each of the four signals is summed across the lane width to create a profile, or trace, consisting of a set of four arrays indicating signal intensities at several thousand uniformly spaced time points during the gel run; trace processing, in which signal processing methods are used to deconvolve and smooth signal estimates, reduce noise, and correct for dye effects on fragment mobility and for long-range electrophorectic trends; and base-calling, in which the processed trace is translated into a sequence of bases (page 175, column 2). As required by claim 1, Ewing et al. describe a system in which nucleic acid data is in the form of a spatial domain (gel), data is transformed (mined), and sequence data is obtained. Furthermore, the spatial domain data is gained from gel electrophoresis and a

obtained. Furthermore, the spatial domain data is gained from gel electrophoresis and a machine-readable format is gathered from the image in the form of a chromatogram (page 176, column 1), as required by claim 2. The goal of the software is to actually produce a sequence as accurate as possible despite data problems, such as compressions, weak or variable signals, and trace spacing. This involves data normalization, as described in detail on pages 176, column 2 and 177, column 1 and required by claim 3. The transformation performed involves the use of the Fourier transformation, as required by claim 6, 18, 30, and 42 (see page 177, column 2).

Ewing et al. do not teach the use of specific data transformation algorithms as in claims 5-9, 17-21, 29-33, and 41-45, however Youssef does speak on data transformation techniques. The lecture includes an overview of various methods of data compression that are utilized in a variety of areas such that data is decorrelated so that fast scalar quantization can be used (page 1). The methods that are typically used include Fourier transformation, wavelet transformation and Hadamard transformation (page 1). It would have been prima facie obvious to one of skill in the art to use the various data transformation techniques in the data transformation process of Ewing et al.

Ewing et al. also do not teach the use of neural networks and classification trees to data mine the transformed data. However, Curram et al. describe a comparison of classification methods which are applicable for classification tasks, such as required by the instant claims 10-12, 22-24, 35-36, and 46-48. Curram describes that neural networks were used to establish relationships between sets of variables. Not only have neural networks been instrumental in investigating how the brain operates, but they have been exploited for their mathematical properties as signal processors (which applies to the instant use) and non-linear statistical models

(page 440, 4th paragraph). The most common network is known as a back propagation network, as in claim 11, which is a layered network with an input layer, hidden layers, and an output layer. This system uses supervised learning in which examples are presented to the network along with their target outputs.

Curram et al. also describe induced rule trees for data mining which include CART. These techniques are useful when data are not deterministic but uncertain (page 443, 3rd paragraph), as could easily be applied to biological sequence data. The uncertainty may be due to noise in the measurements or to the presence of factors which cannot be measured, which could also be applied to sequence data. It would have been prima facie obvious to one of skill in the art to utilize known data mining techniques in order to further assess the data transformed by the method of Ewing et al. In fact it was well known in the art at the time of the invention that biological data mining was growing and that extraction of significant data was important to understand relationships among sequences, genes, proteins etc. (see as a review Ma et al. International Journal on Artificial Intelligence Tools (1993) pages 1-19).

No claims are allowed.

***Inquiries***

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

May 29, 2003

Lori A. Clow, Ph.D.
Art Unit 1631